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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,054	06/28/2000	Maryvonne Chariot	P62285US1	6768

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EXAMINER	
WELLS, LAUREN Q	
ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/605,054	CHARIOT ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/125,840.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-43 are pending.

Response to Applicant's Arguments/Amendment

The Applicant's arguments filed 5/30/03 to the rejection of claims 21-43 made by the Examiner under 35 USC 103 have been fully considered and deemed not persuasive.

103 Rejection Maintained

The rejection of claims 21, 22, 24-26, 30-34, 38 and 39 under 35 U.S.C. 103(a) as being unpatentable over Jang (US 4,590,061) in combination with the HCAPLUS abstract of Desager et al., Pharmacokinetic-pharmacodynamic relationships of H1-antihistamies, Clin. Pharmacokinet. (1995)28(5):419-32 is MAINTAINED for the reasons set forth in the Office Action mailed 12/4/02, and those found below.

The rejection of claims 23, 27-29, 35-37 and 39-43 under 35 U.S.C. 103(a) as being unpatentable over Jang (US 4,590,061) in combination with the HCAPLUS abstract of Desager et al., Pharmacokinetic-pharmacodynamic relationships of H1-antihistamies, Clin. Pharmacokinet. (1995)28(5):419-32, as applied to claims 21, 22, 24-26, 30-34, 38 and 39, and further in view of Acharya (US 5,102,666) is MAINTAINED for the reasons set forth in the Office Action mailed 12/4/02, and those found below.

Applicant argues, "Desager considers common pharmacokinetics of ten second generation H-receptor antagonists, with no particular direction to mizolastine, which is only one member of the considered class". This argument is not persuasive, as Desager specifically teaches mizolastine as a H-receptor antagonist, and the disclosure of this active is not within a laundry list of actives, but is specifically disclosed.

Applicant argues, "Jang is generically directed to dry compressed compositions for controlled release dosage forms. . .Among the hundreds of active components actually mentioned by Jang mizolastine does not even appear". This argument is not persuasive. First, it is respectfully pointed out that the instant rejection is over a combination of reference, and, as pointed out in the instant rejection, Desager is relied upon to specifically teach mizolastine. Second, for the benefits of Desager, there is motivation to teach mizolastine as the antihistamine of Jang. Furthermore, as Applicant points out, Jang is generically directed to dry compressed compositions for controlled release dosage forms, wherein antihistamines are taught as active ingredients, wherein Desager teaches the benefits of mizolastine as an antihistamine, i.e., non drowsiness.

Applicant argues, "there is absolutely no rationale that would lead anyone of ordinary skill in the art to select mizolastine from Desager and antihistamines from Jang. In the absence of Applicants' disclosure, the art itself would not lead to the combination of these two references for any particular purpose". This argument is not persuasive. First, in response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Second, for the reasons stated in the above paragraph and the instant rejection, there is motivation in the prior art.

Regarding the phrase "consisting essentially of", it is respectfully pointed out that for the purposes of searching for an applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Applicant argues, "Jang is not concerned with specific drugs and their needs". This argument is not persuasive. It is respectfully pointed out that Jang teaches the benefits of his formulations for active ingredient delivery, wherein a multitude of drugs can be utilized. Desager is relied upon to show how one of ordinary skill in the art would be motivated to formulate the formulations of Jang with mizolastine.

Applicant argues, "The actual formulations required for the diverse groups mentioned by Jang would vary considerably, and no direction whatsoever is provided with regard to mizolastine. Each of the references relied upon provides nothing more than an invitation to experiment". This argument is not persuasive. See the above paragraphs and the previous Office Action, wherein these arguments have been addressed.

Applicant argues, regarding Desager, "it gives no information concerning a formulation for use, and, consequently, no predictable information concerning the effect of pH on dissolution profile or possible pharmaceutical forms including it". This argument is not persuasive. It is

respectfully pointed out that Desager is merely relied upon to teach the desirability of utilizing mizolastine as an antihistamine active ingredient.

Applicant argues, "The pH independent is one of the major aims of the present invention". This argument is not persuasive, especially since instant independent claim 21 does not even contain such a limitation.

Applicant argues, "Issue is respectfully taken with regard to the burden being shifted to Applicants, particularly in view of the fact that no detailed compositions with antihistamines are shown by any of the applied art, thus making it impossible to compare that which is called for by Applicants' claims with any disclosure in the prior art relied upon". This argument is not persuasive. It is respectfully pointed out that the combination of references teaches the same formulations as recited in the instant claims. Since a compound, and hence a formulation, and its properties are inseparable, the combined references have the pH independent dissolution profile, as recited in the instant claims.

Applicant argues, "There is nothing in the applied art that would even remotely suggest that Applicants' claimed tablets would be pH independent, would permit 100% release of the active component in five hours, would have an in vivo mizolastine release which prevents any plasma peak, or wherein mizolastine bioavailability is not decreased relative to that of an immediate release formulation". This argument is not persuasive. First, this argument is not even commensurate in scope with the instant independent claims, which do not even recited such limitations. Second, as pointed out above, the combination of references teaches the same formulations as recited in the instant claims. Since a compound, and hence a formulation, and its

properties are inseparable, the combined references have the pH independent dissolution profile and other properties, as recited in the instant claims.

Applicant argues, "There is no reason that anyone of ordinary skill in the art would consult this reference in dealing with the problems faced and solved by Applicants' claimed invention. Moreover, Acharya is generically concerned with an excess of 30 different classes of drugs". This argument is not persuasive. It is respectfully pointed out that Acharya is merely relied upon to teach the conventionality of adding tartaric acid to controlled release tablets containing antihistamines.

Applicant argues, "Please not that the reference to tartaric acid by Acharya is clearly and solely optional. There is absolutely no reason to believe from Acharya that addition of tartaric acid could improved the efficacy of a pharmaceutical formulation, as provided by Applicants' claimed invention". This argument is not persuasive. First, it is respectfully pointed out that the instant rejection does not attempt, in the motivation to combine the references, to improve the efficacy of the formulation, as argued. Second, it is respectfully pointed out that Acharya teaches the benefits of adding tartaric acid to controlled release tablets containing antihistamines, i.e., flavoring and breath freshening. For this reason alone, there is motivation to add tartaric acid to the formulations of the combined references.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is 571-272-0634. The examiner can normally be reached on M&R (5:30-4).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

lqw

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER